R E M A R K S

Careful review and examination of the subject application are noted and appreciated.

SUPPORT FOR THE CLAIM AMENDMENT

The amendment to claim 19 line 14 concerns formatting and should only require a cursory review by the Office. Thus, no new matter has been added and no new issues are believed to be raised. As such, entry of the amendment is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

The rejection of claims 1-7, 9-16 and 18-22 under 35 U.S.C. §102(e) as being anticipated by Papageorge '445 is respectfully traversed and should be withdrawn.

Papageorge concerns a medical system for shared patient and physician decision making (title).

In contrast, the present invention provides a server having a questionnaire generator, a database and a profile generator. The questionnaire generator may be for (i) generating a questionnaire comprising (a) one or more questions for determining an expression of risk for an individual, (b) a first number of answer options to each of the questions and (c) one or more follow-up actions. The expression of risk generally concerns at least one of a physical condition of the individual, a mental

condition of the individual, and a behavior of the individual. The questionnaire generator may also be for (ii) associating each of the answer options with one of a second number of values representing a level of risk, the second number of values being greater than the first number of answer options and (iii) transmitting the questionnaire from the server to an apparatus. The apparatus is generally (a) associated with the individual and (b) remotely located from the server. The database may be in a storage medium. The database generally contains model information relating to (i) an aspect of care, (ii) the expression of risk and (iii) the level of risk. The profile generator may be for (i) generating a profile for the individual based on one or more of the aspects of care, responses to the questions, the expression of risk and the level of risk associated with the individual and (ii) sending health related information to the individual based on the profile. The data relating to the physical condition of the individual generally comprises patient information from one or more medical claims received by the server from a medical claims paying organization associated with the individual.

Claims 1 and 10 are independently patentable over the cited reference. Claim 1 provides a questionnaire generator for (i) generating a questionnaire comprising (a) one or more questions for determining an expression of risk for an individual, the expression of risk concerning at least one of a physical condition

of the individual, a mental condition of the individual and a behavior of the individual. Claim 10 provides similar language. The Office Action cites the text in (ii) column 8 line 4 to column 9 line 33 and (ii) column 11 lines 15-30 of Papageorge in rejecting the above claim limitations. In contrast, the cited text and the rest of Papageorge appears to be silent regarding an expression of risk of an individual. Therefore, *prima facie* anticipation has not been established for lack of evidence that the reference describes all of the claim limitations as arranged in the claims.

In particular, the text in column 8 line 4 to column 9 line 33 of Papageorge reads:

> Chart 1 sets forth how a CHES system for chronic mitral valve disease would work compared to present treatment selection option.
> Chart 2 describes the CHES method in more detail.
> Building a CHES System:
> CHES derives much value in its unique development process outlined below.
> 1. Describing the Disease:
> a. Determine the etiologies, forms, and natural history of a disease.
> b. Determine its incidence and prevalence rates in the population.
> c. Identify all treatments that can be used.
> d. Identify how patient factors, lesion, and severity of disease dictate treatment.
> e. Resolve whether one treatment is favored despite factors in each case, and why.
> 2. Assessing Treatments:
> a. Collect and analyze treatment **outcome data from published follow-up studies.**
> b. Stratify data by specific lesion of disease, treatment used, demographics, and time frame.
> c. Document (for further investigation) whether treatments are selected based on clinical factors or as a matter of practice style.
> d. Ascertain any correlation between treatments and patient factors, or practice style, (e.g., treat early symptoms vs. not treating until symptoms are serious).
> e. Use the treatment with the statistically best outcomes as the basis for a **risk assessment scale** for computing patients' **risk tolerance level.**
> f. Prepare interview schedule on disease, customary and lesser-used treatments for known **medical experts** (who may differ in their views) to explain in terms of practice patterns. Have them score specific clinical indicators for treatment, and give three value ranges for each indicator; Normal, Suspect, and Severe.
> g. Ask experts to reconcile practice views with published outcomes statistics to assess effect of practice patterns on treatment selection.
> h. Conduct cost-effectiveness analysis to compare costs of each treatment to survival, continued morbidity, and mortality.
> 3. System Components

a. Use cost and outcome data, from the steps above, to indicate trade-offs for patients to consider in selecting, with their physicians, a suitable treatment.

b. Quantify these trade-offs using discount rates to score patients' risk tolerance for each treatment strategy, showing the proximity of treatment preferences to what is most cost-effective.

c. Develop **patient questionnaire** to elicit treatment preferences and their bases, e.g., economic, family, lifestyle, and **fear of surgical risk**, pain, etc., which may change his/her risk tolerance level.

d. Develop **physician questionnaire** on patients' clinical condition, severity level, planned treatment, and why others are not appropriate for a given patient.

e. Apply **risk tolerance scale** to the reasons for preferences to construct a **risk tolerance profile** of the patient.

f. Use cost-effectiveness analysis results to compute estimated direct **medical cost** of treatment and indirect costs resulting from inability to work or perform other tasks measurable by the concept of human capital.

g. Write conditional text for each possible physician and **patient questionnaire response**, explaining its positive or negative impact on outcome.

h. Format a report showing the responses and conditional text, the patient's risk tolerance profile, patient and physician treatment preferences, how they compare to that found to be most cost-effective, and the factors supporting their choice. Compute direct and indirect costs of each treatment option. Also, show the patient's severity level based on aggregate scores of the clinical indicators. Provide a one-page summary of the same information for use by insurers.

At this point, each system will be shown to physicians at different centers for comments and suggested changes, followed by testing with other physicians and their pre-treatment patients. Care will be taken to ensure properly selected patients and to prevent use of this test to make an actual treatment decision. They are only to use the system and provide feedback as to its utility and its accuracy in profiling the clinical and non-clinical factors in each case.

Chart 3 sets forth the CHES system development process in general. This development process will be repeated for all systems, with variations as needed to accommodate different diseases and their treatments. This process is tedious and will require varying amounts of time to complete for each system. It is for this reason that this plan projects a three-year development time frame. Ways will be sought to expedite this process without compromising accuracy. (Emphasis added)

The cited text on column 11 lines 15-30 of Papageorge reads:

2. Processing Phase:

a. Cost formulas for a set time frame for each treatment option. (Components of formulas: direct and indirect medical costs, complication rates, mortality rates, potential loss of earnings, discount rates.)

b. Discount rates assigned to responses to quantify each patient's risk tolerance.

c. **Preassigned levels of risk** (0-9 scale) for each possible response are computed.

d. Different data sets of post-treatment complication incidence rates are selected depending on the type of lesion.

e. Text representing physician's and patient's responses are generated.

3. Output Phase:

a. Data entered is quantified and integrated into a hard-copy report on real time basis.

b. Graphics and conditional text are included to enhance user interpretation. (Emphasis added)

The above cited text of Papageorge appears to discuss (i) a risk assessment scale, (ii) a risk tolerance level, (iii) fear of surgical risk, (iv) a risk tolerance scale, (v) a risk tolerance profile and (vi) preassigned levels of risk. However, nowhere in the cited text, or in any other section does Papageorge appear to mention anything that one of ordinary skill in the art could consider similar to the claimed expression of risk. Papageorge also appears to be silent regarding the alleged expression of risk being determined by a questionnaire comprising one or more questions. Furthermore, Papageorge appears to be silent regarding the alleged expression of risk concerning any of a physical condition, a mental condition and a behavior condition of the patient. Therefore, Papageorge does not appear to disclose a questionnaire generator for generating a questionnaire comprising one or more questions for determining an expression of risk for an individual, the expression of risk concerning at least one of a physical condition of the individual, a mental condition of the individual and a behavior of the individual, as presently claimed.

Claim 1 further provides that the questionnaire generator is for (i) generating (c) one or more follow-up actions. Claim 10 provides similar language. The Office Action again cites the text in (ii) column 8 line 4 to column 9 line 33 and (ii) column 11 lines 15-30 of Papageorge (reproduced above) in the rejection. In contrast, the cited text and the rest of Papageorge appears to be

silent regarding follow-up questions in the questionnaire. Therefore, *prima facie* anticipation has not been established for lack of evidence that the reference describes all of the claim limitations as arranged in the claims.

In particular, the cited text of Papageorge appears to indicate that the patient questionnaire poses questions to which a patient can respond. However, the cited text and the rest of Papageorge appears to be silent regarding the questionnaire having follow-up actions. In particular, the text of Papageorge in column 8 lines 58-59 states that the purpose of the patient questionnaire is "to elicit treatment preferences and their bases". Nothing is said about follow-up actions. Therefore, Papageorge does not appear to describe a questionnaire generator for generating one or more follow-up actions, as presently claimed.

Claim 1 further provides that the questionnaire generator (ii) associates each of the answer options with one of a second number of values representing a level of risk, the second number of values being greater than the first number of answer options. Claim 10 provides similar language. The Office Action again cites the text in (ii) column 8 line 4 to column 9 line 33 and (ii) column 11 lines 15-30 of Papageorge (reproduced above) in rejecting the above claim limitations. However, the cited text and the rest of Papageorge appears to be silent regarding (i) the number of response options to the questions and (ii) the number of response

options being less than a number of values representing a level of risk. Therefore, *prima facie* anticipation has not been established for lack of evidence that the reference describes all of the claim limitations as arranged in the claims.

In particular, the text in column 11 lines 21-22 of Papageorge indicates ten levels of risk (0-9) associated each possible response are computed. However, Papageorge appears to be silent that less than ten response options exist in the questionnaire. Papageorge does not appear to make any associations between the number of answer options and the ten levels of risk. Therefore, Papageorge does not appear to describe a questionnaire generator that associates each of the answer options with one of a second number of values representing a level of risk, the second number of values being greater than the first number of answer options, as presently claimed.

Claim 1 further provides a database in a storage medium, the database containing model information relating to (i) an aspect of care, (ii) the expression of risk and (iii) the level of risk. Claim 10 provides similar language. The Office Action cites the text in column 8 line 4 to column 9 line 33 of Papageorge (reproduced above) in the rejection. However, the cited text and the rest of Papageorge appears to be silent regarding (i) model information and (ii) the model information comprising an aspect of care. Therefore, *prima facie* anticipation has not been established

for lack of evidence that the reference describes all of the claim limitations as arranged in the claims.

In particular, the cited text and the rest of Papageorge appears to be silent regarding any models and anything that one of ordinary skill in the art could consider to be similar to the claimed aspect of care. Therefore, Papageorge does not appear to describe a database in a storage medium, the database containing model information relating to (i) an aspect of care, (ii) the expression of risk and (iii) the level of risk, as presently claimed.

Claim 1 further provides that the physical condition of the individual comprises patient information from one or more medical claims received by the server from a medical claims paying organization associated with the individual. The Office Action again cites the text in column 8 line 4 to column 9 line 33 of Papageorge (reproduced above) in rejecting the above claim limitations. However, the cited text and the rest of Papageorge appears to be silent regarding (i) the reception of medical claims at the CHES from (ii) a medical claims paying organization associated with the patient. Therefore, *prima facie* anticipation has not been established for lack of evidence that the reference describes all of the claim limitations as arranged in the claims.

In particular, Papageorge column 6 lines 43-47 appears to contemplate that the CHES system is used before any treatment is

performed and thus before medical claims are made. Furthermore, Papageorge appears to be silent regarding (i) the computerized health evaluation system receiving medical claims from (ii) a medical claims paying organization. The only "claims" mentioned by Papageorge appear to be the patent claims. Therefore, Papageorge does not appear to describe that the physical condition of the individual comprises patient information from one or more medical claims received by the server from a medical claims paying organization associated with the individual, as presently claimed. As such, the claimed invention is fully patentable over the cited reference and the rejection should be withdrawn.

Claim 19 is independently patentable over the cited reference. Claim 19 provides (A) displaying a plurality of icons of a plurality of questions, a plurality of answers, a plurality of follow-up actions and a plurality of follow-up answers. The Office Action cites (i) column 8 line 4 to column 9 line 33 (reproduced above) and (ii) the Abstract of Papageorge in the rejection. However, the cited text and the rest of Papageorge appears to be silent regarding icons of (i) questions, (ii) answers, (iii) follow-up actions and (iv) follow-up answers. Therefore, *prima facie* anticipation has not been established for lack of evidence that the reference describes all of the claim limitations as arranged in the claims.

The text of Papageorge in column 8 line 4 to column 9 line 33 is reproduced above. The Abstract of Papageorge reads:

> A computerized health evaluation system for joint patient and physician decision making concerning particular medical diseases and conditions. The system includes a computer system with a patient input module for patient input of patient data concerning the patient's lifestyle and preferences, a physician input module for physician input of physical and physiological data, and a database of the latest medical findings concerning the particular disease and condition. The computer system uses an algorithm for weighing the patient data and the physician data in view of the database and generating a report setting forth various treatment options. Based upon the report, the patient and physician will jointly decide on a treatment approach.

Nowhere in the cited text, or in any other section does Papageorge appear to mention icons of any kind. In particular, the word "icon" is not used in the text of Papageorge. Nothing is said about question icons, answer icons, follow-up action icons or follow-up answer icons. Therefore, Papageorge does not appear to describe displaying a plurality of icons of a plurality of questions, a plurality of answers, a plurality of follow-up actions and a plurality of follow-up answers.

Claim 19 further provides (B) receiving a selection to each of a particular question of the questions, a particular answer of the answers, a particular follow-up action of the follow-up actions and a particular follow-up answer of the follow-up answers from a user. The Office Action again cites (i) column 8 line 4 to column 9 line 33 and (ii) the Abstract of Papageorge (reproduced above) in the rejection. However, the cited text and the rest of Papageorge appears to be silent regarding selections of (i) a particular question, (ii) a particular answer, (iii) a particular follow-up action and (iv) a particular follow-up answer.

Therefore, *prima facie* anticipation has not been established for lack of evidence that the reference describes all of the claim limitations as arranged in the claims.

In particular, the cited text and the rest of Papageorge appears to be silent regarding any selections. Papageorge appears to be silent regarding follow-up actions. Papageorge appears to be silent regarding follow-up answers. Therefore, Papageorge does not appear to describe receiving a selection to each of a particular question of the questions, a particular answer of the answers, a particular follow-up action of the follow-up actions and a particular follow-up answer of the follow-up answers from a user, as presently claimed.

Claim 19 further provides (C) linking the particular icons. The Office Action cites column 8 line 4 to column 9 line 33 of Papageorge (reproduced above) in the rejection. However, the cited text and the rest of Papageorge appears to be silent regarding linking of icons. Therefore, *prima facie* anticipation has not been established for lack of evidence that the reference describes all of the claim limitations as arranged in the claims.

As noted above, Papageorge does not mention icons. Papageorge appears to be silent regarding follow-up actions. Papageorge appears to be silent regarding follow-up answers. In the absence of the particular icons, one of ordinary skill in the art would not understand Papageorge to allegedly explain how to

link the non-existing icons. Therefore, Papageorge does not appear to describe linking the particular icons, as presently claimed.

Claim 19 further provides (D) converting the linked icons into a questionnaire. The Office Action again cites column 8 line 4 to column 9 line 33 of Papageorge (reproduced above) in the rejection. However, the cited text and the rest of Papageorge appears to be silent regarding converting icons into a questionnaire. Therefore, *prima facie* anticipation has not been established for lack of evidence that the reference describes all of the claim limitations as arranged in the claims.

Papageorge does not mention icons. Hence, one of ordinary skill in the art would not understand Papageorge to allegedly explain how to convert the non-existing icons into a questionnaire. Therefore, Papageorge does not appear to describe converting the linked icons into a questionnaire, as presently claimed. As such, claim 19 is fully patentable over the cited reference and the rejection should be withdrawn.

Claims 3, 12 and 21 are independently patentable over the cited reference. Claim 3 further provide that a profile comprises a language of an individual. Claims 12 and 21 provides similar language. The Office Action cites column 7 line 65 to column 8 line 4 of Papageorge in the rejection. However, the cited text and the rest of Papageorge appears to be silent regarding a language of the patient. Therefore, *prima facie* anticipation has not been

established for lack of evidence that the reference describes all of the claim limitations as arranged in the claims.

In particular, the cited text of Papageorge reads:

> Treatment, disease subcategories, concurrent conditions (related or unrelated), patient demographics, and any effect of recent medical advances in each treatment stratify the data from these studies as they may affect outcomes of one treatment over another. These elements are then used to evaluate the costs, risks, and benefits of competing treatments.

The above cited text mentions patient demographics, but not a language of the patient. Furthermore, the text of Papageorge does not even mention the word "language". Therefore, Papageorge does not appear to describe that a profile comprises a language of an individual, as presently claimed. As such, claims 3, 12 and 21 are fully patentable over the cited reference and the rejections should be withdrawn.

Claim 4 is independently patentable over the cited reference. Claim 4 provides (from claim 1) a profile for the individual, (from claim 4) (ii) a motivational profile and (from claim 4) (iii) a comprehensive capacity profile. The Office Action cites column 8 line 4 to column 9 line 33 of Papageorge (reproduced above) in the rejection. However, the cited text and the rest of Papageorge appears to be silent regarding three types of profiles. Therefore, *prima facie* anticipation has not been established for lack of evidence that the reference describes all of the claim limitations as arranged in the claims.

In particular, the cited text of Papageorge only appears to mention a risk tolerance profile. One of ordinary skill in the

art would understand that the single risk tolerance profile of Papageorge could match at best one of the three claimed profiles. The rest of Papageorge appears to be silent regarding any other types of profiles. Therefore, Papageorge does not appear to describe a profile for the individual, a motivational profile and a comprehensive capacity profile, as presently claimed. As such, claim 4 is fully patentable over the cited reference and the rejection should be withdrawn.

Claims 7 and 16 are independently patentable over the cited reference. Claim 7 further provides one or more measurements received by the server from a monitoring device connected to the apparatus. Claim 16 provides similar language. The Office Action again cites column 8 line 4 to column 9 line 33 of Papageorge (reproduced above) in the rejection. However, the cited text and the rest of Papageorge appears to be silent regarding any monitoring type device connected to an Internet terminal that could measure the patient. Therefore, *prima facie* anticipation has not been established for lack of evidence that the reference describes all of the claim limitations as arranged in the claims.

In particular, column 8 lines 23-34 of Papageorge mentions "outcome data" from published follow-up studies. However, Papageorge appears to be silent that the outcome data is measured from the patient by a monitoring device. In contrast, the CHES system appear to operate before any testing is done on the patient.

Therefore, Papageorge does not appear to describe one or more measurements received by the server from a monitoring device connected to the apparatus, as presently claimed. As such, claims 7 and 16 are fully patentable over the cited reference and the rejections should be withdrawn.

Claims 9 and 18 are independently patentable over the cited reference. Claim 9 further provides medical information from electronic medical records received by the server from a services organization associated with the individual. Claim 18 provides similar language. The Office Action again cites column 8 line 4 to column 9 line 33 of Papageorge (reproduced above) in the rejection. However, the cited text and the rest of Papageorge appears to be silent regarding electronic medical records being provided from a services organization. Therefore, *prima facie* anticipation has not been established for lack of evidence that the reference describes all of the claim limitations as arranged in the claims.

In particular, the cited text of Papageorge only appears to mention (i) medical experts and (ii) medical costs. Papageorge appears to be silent regarding anything that one of ordinary skill in the art could consider being similar to the claimed electronic medical records. Furthermore, Papageorge appears to be silent regarding a services organization providing the non-existing electronic medical records. Therefore, Papageorge does not appear to describe medical information from electronic medical records

received by the server from a services organization associated with the individual, as presently claimed. As such, claim 9 and 18 are fully patentable over the cited reference and the rejections should be withdrawn.

Claim 22 is independently patentable over the cited reference. Claim 22 further provides simulating the questionnaire prior to the transmission of the questionnaire to the one or more patient devices. The Office Action again cites column 8 line 4 to column 9 line 33 of Papageorge (reproduced above) in the rejection. However, the cited text and the rest of Papageorge appears to be silent regarding simulations. Therefore, *prima facie* anticipation has not been established for lack of evidence that the reference describes all of the claim limitations as arranged in the claims. As such, claim 22 is fully patentable over the cited reference and the rejection should be withdrawn.

Claims 2-9, 11-18 and 20-22 depend, either directly or indirectly, from claims 1, 10 or 19, which are now believed to be allowable. As such, the dependent claims are fully patentable over the cited reference and the rejections should be withdrawn.

Accordingly, the present application is in condition for allowance. Early and favorable action by the Examiner is respectfully solicited.

The Examiner is respectfully invited to call the Applicant's representative at 586-498-0670 should it be deemed beneficial to further advance prosecution of the application.

If any additional fees are due, please charge Deposit Account No. 50-0541.

Respectfully submitted,

CHRISTOPHER P. MAIORANA, P.C.

Christopher P. Maiorana
Registration No. 42,829

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c/o Sandeep Jaggi
Health Hero Network

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